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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
| 08/731,499 | 10/16/98 | GRAY | J 023070-06891 |

HM11/0217
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EXAMINER

UNGAR, S
ART UNIT PAPER NUMBER

1642 14
1642

DATE MAILED: 02/17/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 12-5-97

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 30 days month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-44 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-44 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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1. The Election filed December 5, 1997 (Paper No. 13) in response to the Office Action of November 12, 1997 (Paper No. 12), 1996 is acknowledged and has been entered. Claims 1-44 are currently being examined.

2. Upon review and reconsideration, the restriction requirement of November 12, 1997 has been vacated, thus the arguments presented in Paper No. 12 in traverse of the restriction requirement are moot.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group I. Claims 1-23 are drawn to an isolated nucleic acid molecule classified in Class 536, subclass 23.1.

Group II. Claims 24-38 are drawn to a method of screening neoplastic cells with a polynucleotide probe, classified in Class 435, subclass 6.

Group III. Claims 39-40 are drawn to a method of screening for neoplastic cells with an antibody, classified in Class 435, subclass 7.1.

Group IV. Claims 41, 43 and 44 are drawn to a method of inhibiting the pathological proliferation of cancer cells, classified in Class 424, subclass 130.1.

Group V. Claim 42 is drawn to a method of detecting cancer by detecting over expression of a protein, classified in Class 424, subclass 130.1

4. The inventions are distinct, each from the other because of the following reasons:

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The inventions of Groups II-V are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups I and II/IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the nucleic acid molecule product as claimed can be used in a materially different process such as expressing the protein product encoded by the nucleic acid molecule.

The inventions of Groups I and III/V are not at all related because the isolated nucleic acid molecule of Group I is not used in the methods of Groups III/V.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Group I is further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising isolated nucleic acid molecules which specifically hybridize to sequences with different structures and therefore different functions wherein the sequences are (a) SEQ ID NO. 2 (claims 1-3), (b) SEQ ID NO. 3 (claims 1, 4 and 5), (c) SEQ ID NO. 4 (claims 1, 6 and 7), (d) SEQ ID NO. 5 (claims 1, 8

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and 9), (e) SEQ ID NO. 6 (claims 1, 10 and 11), (f) SEQ ID NO. 7 (claims 1, 12 and 13), (g) SEQ ID NO. 8 (claims 1, 14 and 15), (h) SEQ ID NO. 9 (claims 1, 16 and 17), (i) SEQ ID NO. 10 (claims 1, 18 and 19), (j) SEQ ID NO. 12 (claims 1, 20 and 21). Claims 22 and 23 will be examined as they are drawn to the elected species.

7. Group II is further subject to election of a single disclosed species.

Claim 24 is generic to a plurality of disclosed patentably distinct species comprising a method of screening for neoplastic cells in a sample comprising contacting a nucleic acid sample with a probe which hybridizes to sequences with different structures and therefore different functions wherein the sequences are (a) SEQ ID NO. 1 (claims 24 and 27), (b) SEQ ID NO. 2 (claims 24 and 28), (c) SEQ ID NO. 3 (claims 24 and 29), (d) SEQ ID NO. 4 (claims 24 and 30), (e) SEQ ID NO. 5 (claims 24 and 31), (f) SEQ ID NO. 6 (claims 24 and 32), (g) SEQ ID NO. 7 (claims 24 and 33), (h) SEQ ID NO. 8 (claims 24 and 34). Claim 38 will be examined as it is drawn to the elected species.

8. Group III is further subject to election of a single disclosed species.

Claim 39 is generic to a plurality of disclosed patentably distinct species comprising a method of screening for neoplastic cells in a sample comprising contacting a sample with an antibody that specifically binds to a polypeptide antigen encoded by different polynucleotide sequences therefore encoding protein products with different structures and functions wherein the sequences are (a) SEQ ID NO. 1, (b) SEQ ID NO. 2, (c) SEQ ID NO. 3, (d) SEQ ID NO. 4, (e) SEQ ID NO. 5, (f) SEQ ID NO. 6, (g) SEQ ID NO. 7, (h) SEQ ID NO. 8,

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(i) SEQ ID NO. 9, (j) SEQ ID NO. 10, (k) SEQ ID NO. 12. Claim 40 will be examined as it is drawn to the elected species.

9. Group IV is further subject to election of a single disclosed species.

Claim 41 is generic to a plurality of disclosed patentably distinct species comprising a method of inhibiting the pathological proliferation of cancer cells comprising inhibiting the activity of a gene product which hybridizes to different sequences and therefore produce different gene products with different structures and functions, wherein the sequences are (a) SEQ ID NO. 1, (b) SEQ ID NO. 2, (c) SEQ ID NO. 3, (d) SEQ ID NO. 4, (e) SEQ ID NO. 5, (f) SEQ ID NO. 6, (g) SEQ ID NO. 7, (h) SEQ ID NO. 8, (i) SEQ ID NO. 9, (j) SEQ ID NO. 10, (k) SEQ ID NO. 12. Claims 43 and 44 will be examined as they are drawn to the elected species.

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

13. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 308-305-2181.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached at (703) 308-2731. The fax phone number for this Art Unit is (703) 308-4065.

Communications via Internet e-mail regarding this application, other than those under 35 USC 132 or which otherwise require a signature may be used by the applicant and should be addressed to lila.feisee@uspto.gov.

All internet e-mail communications will be made of record in the application file. **PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified**

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or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of USC 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar

February 11, 1998


LILA FEISEE
SUPERVISORY PATENT EXAMINER
GROUP 1800 / 1642